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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,340	03/06/2007	Larry Lapanashvili	088790-000300US	6589

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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
06/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,340	LAPANASHVILI, LARRY	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/24/10 & 3/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 15, 17-22, 24-28, 30 & 32** are rejected under 35 U.S.C. 102(b) as being anticipated by May (US 2003/0176901).

May discloses an electrotherapy apparatus (e.g., element 1) and method for applying electrical stimulation to a muscle or group of muscles [e.g., 0001], wherein said electrical stimulation comprises electrical pulses, said electrical stimulation having parameters comprising at least some of an amplitude, a pulse repetition frequency, etc., and a microprocessor (e.g., element 6) adapted to vary at least one of said amplitude, frequency, etc. in accordance with a predetermined pattern stored in the associated microprocessor (e.g., via disclosed memory, element 7) within pre-specified limits in the course of the treatment extending over many heart cycles (e.g., [0051]-[0053], [0059] & [0077]), wherein the plurality of said parameters are simultaneously varied [e.g., 0049]. NOTE, the examiner has chosen amplitude and frequency, therefore, the other dependent claims that do not first set forth which parameter the claimed method or device has (such as duration) have been met.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 16 & 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over May (US 2003/0176901).

May discloses the claimed invention having an apparatus and a method for applying electrical stimulation by way of varying the stimulation's amplitude except wherein said variation of amplitude is in a range from ± 10 V from a nominal value selected in the range from typically 10 to 50 V. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and method as taught by May with utilizing a variation of the amplitude in the range from ± 10 V from a nominal value selected in the range from typically 10 to 50 V since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233].

5. **Claims 29 & 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over May (US 2003/0176901).

May discloses the claimed invention having an apparatus and a method for applying electrical stimulation by utilizing a microprocessor having pre-specified limits in the course of an extended treatment except wherein said treatment lasts for more than 15 minutes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to extend said treatment for more than 15 minutes, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

6. Applicant's arguments filed 24 February 2010 have been fully considered but they are not persuasive. The Applicant argues that May fails to disclose, teach and/or suggest the claimed invention due to the following points. Each argument will be respectfully followed with why the Examiner disagrees with the argument point.

- The Applicant states that May is not directed to curing adverse conditions of the human or mammalian heart as is the case in the present application.

The Examiner disagrees and further points out that the disclosed electro-therapeutic device as disclosed by May, that applies a treatment current characterized by a plurality of stimulating parameters is capable of curing adverse conditions of the human/mammalian heart as is argued since the disclosed stimulation parameters and electrodes of the electrotherapy device can deliver electrical stimulating current to the heart, wherein said current can treat adverse conditions of the heart, as is instantly claimed (e.g., [0001] & [0051]-[0053]). Also note that the claims do not positively recite that the method and/or apparatus must cure said adverse conditions of the heart since the claims language presently uses a functional use recitation of "…for applying electrical stimulation to a muscle or group of muscles…" and as long as the prior art is capable of performing the functional use recitation the claim limitation is met, as is explained above.

- The Applicant states that May does not disclose, teach and/or suggest the claim limitation of varying at least one of said amplitude, pulse repetition frequency, etc., "…in accordance with a predetermined patterned stored in a microprocessor or a random number generator..."

The Examiner disagrees and further points out that May discloses a fixed parameter used by the electro-therapy device that is "adjusted," i.e. varied, via utilizing an "operating memory/processor" of said device in which stores values of said parameters and uses said values to adjust and/or vary the parameters based, in which said parameters are further used to automatically control the steps of delivering the therapy, wherein said parameters stored within the "memory/processor" are **preset**, i.e. predetermined (e.g., [0053] & [0059]).

- The Applicant states that May fails to disclose the claim limitation pertaining to the stimulation pulses with "…time offset relative to the predicted end of a T wave of an electrocardiogram derived form said person or mammal…" and/or the possibility of synchronizing the stimulation pulses the heart rate, i.e. with the T-wave.

The Examiner agrees with the above argument however points out that the argument is moot since the claims call for "...at least some of an amplitude, pulse repetition frequency...a time offset relative to a predicted end of a T-wave..." and the prior art is then only required to disclose "at least SOME" in which the examiner has chosen amplitude and frequency. In other words, the claims do not require ALL of the limitations listed, just at least TWO since that is considered to be the broadest interpretation of "some." Therefore, the other dependent claims that do not first set forth which parameter the claimed method or device has (such as duration and/or time offset) have been met.

- The Applicant argues that May does not disclose that the varied frequency ranges from the claimed range of "20 to 1000Hz" since the disclosed frequency range of May falls from the range of 4,096 to 32,768 Hz as is cited in (column 8, line 21) of May and

therefore May is not directed to curing adverse conditions of the human or mammalian heart.

The Examiner agrees with the above argument but further notes that May also discloses the use of a generated treatment current defined by a middle frequency range from 1 to 100 kHz, thus providing a frequency within the claimed frequency range [e.g., 0037]. Also note that the disclosed medium frequency range is used to introduce said frequency into the body to be treated, wherein said frequency range can be applied to the heart in order to cure adverse conditions of the human or mammalian heart as is instantly claimed (e.g., [0001] & [0051]-[0053]).

7. Applicant's arguments, filed 24 February 2010, with respect to the 112, second paragraph rejections have been fully considered and are persuasive and have been withdrawn

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762